



Arbutus Biopharma and Antios Therapeutics Announce Clinical Collaboration Agreement to Evaluate AB-729 in Combination with ATI-2173 in Subjects with Chronic Hepatitis B Virus Infection

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MENDHAM, N.J. and WARMINSTER, Pa., June 29, 2021 (GLOBE NEWSWIRE) -- Antios Therapeutics, Inc. and Arbutus Biopharma Corporation (Nasdaq: ABUS) today announced that the companies have entered into a clinical collaboration agreement to evaluate a triple combination of Arbutus' proprietary GalNAc delivered RNAi therapeutic, AB-729, Antios' proprietary active site polymerase inhibitor nucleotide (ASPIN), ATI-2173, and Viread (tenofovir disoproxil fumarate), for the treatment of subjects with chronic hepatitis B virus (HBV) infection.

ATI-2173, AB-729 and Viread will be evaluated in combination in a single cohort in the ongoing Antios Phase 2a ANTT201 clinical trial. The multi-center, double-blinded, placebo-controlled, multiple-dose cohort will evaluate the safety, pharmacokinetics, immunogenicity, and antiviral activity of the combination of ATI-2173, AB-729 and Viread. This cohort is expected to initiate in the second half of 2021. Antios will be responsible for the costs of adding this single cohort to its ongoing clinical trial. Arbutus will be responsible for the manufacture and supply of AB-729.

"This collaboration with Antios advances our efforts to position AB-729 as a potential cornerstone therapeutic in future HBV combination regimens and reflects our conviction that a combination of agents with complementary mechanisms of action is needed to cure chronic HBV," stated William Collier, Chief Executive Officer at Arbutus."

Greg Mayes, Chief Executive Officer of Antios said, "ATI-2173 has, to date, demonstrated a well-tolerated safety profile and sustained on- and off-treatment antiviral responses as a monotherapy in patients with chronic HBV. We believe that its unique mechanism of action and early evidence of clinical activity may position ATI-2173 as the backbone of a once-daily curative regimen in combination with other agents for chronic HBV. Our collaboration with Arbutus will test that hypothesis in combination with AB-729, an RNAi drug candidate, and Viread, a nucleotide analogue."

About the Combination Clinical Trial Cohort

The combination clinical trial cohort will include 10 subjects with chronic HBV infection assigned 8:2 to active drug (ATI-2173+AB-729) or matching placebos. The active drug (ATI-2173+AB-729) or placebo will be administered in combination with 300 mg of Viread (equivalent to 245 mg of tenofovir disoproxil fumarate). ATI-2173 and Viread will be administered once a day for 90 days. AB-729 will be administered by subcutaneous injection at Day 28 and Day 90. Following this 90 day treatment period, subjects will be followed-up for safety and sustained antiviral responses for 6 additional months.

Any subjects whose HBV DNA remains below the limit of quantification (BLQ) at 6 months of follow-up will have HBV DNA and virology samples collected every 3 months off therapy until a detectable HBV DNA level is confirmed, or until 18 months after the 6 months of follow-up, whichever comes first.

About AB-729

AB-729 is an RNA interference (RNAi) therapeutic targeted to hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. AB-729 inhibits viral replication and reduces all HBV antigens, including hepatitis B surface antigen in preclinical models. Reducing hepatitis B surface antigen is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. Based upon clinical data generated thus far in an ongoing single- and multi-dose Phase 1a/1b clinical trial, AB-729 has demonstrated positive safety and tolerability data and meaningful reductions in hepatitis B surface antigen.

About ATI-2173

ATI-2173 is a novel, orally-administered, liver-targeted Active Site Polymerase Inhibitor Nucleotide (ASPIN) molecule designed to deliver the 5'-monophosphate of clevudine to the liver. This L-nucleoside's active 5'-triphosphate has unique antiviral properties as a non-competitive, non-chain terminating HBV polymerase inhibitor that distorts the active site of HBV polymerase resulting in potent HBV antiviral activity and extended off-treatment suppression of HBV DNA. ATI-2173 targets the liver, delivering high levels of the unique 5'- triphosphate while limiting systemic exposure to the parent L-nucleoside. ATI-2173 has the potential to become an integral part of a curative combination regimen for chronic hepatitis B.

About HBV

Hepatitis B is a potentially life-threatening liver infection caused by HBV. HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection (CHB) represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

About Arbutus

Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company primarily focused on discovering, developing and commercializing a cure for people with chronic hepatitis B virus (HBV) infection. The Company is advancing multiple product candidates with distinct mechanisms of action that it believes have the potential to provide a new curative regimen for chronic HBV infection. Arbutus has also initiated a drug discovery and development effort for treating coronaviruses (including COVID-19). For more information, visit www.arbutusbio.com.

About Antios

Antios Therapeutics is a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat and cure viral diseases. Antios is currently developing ATI-2173, aiming to provide chronic hepatitis B-infected patients with a curative combination regimen.

Arbutus Forward-Looking Statements and Information

This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward-looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Forward-looking statements in this press release include statements about our expectations for the collaboration; the timing and expected trial design of the Phase 2a clinical trial to be initiated by the parties pursuant to the agreement; and Arbutus' belief that AB-729 has the potential to become a cornerstone therapeutic in multiple future HBV combination regimens.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies, including uncertainties and contingencies related to the ongoing COVID-19 pandemic.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: the parties may never realize the expected benefits of the collaboration; anticipated clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; economic and market conditions may worsen; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt clinical development programs.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic disclosure filings, which are available at www.sedar.com and at www.sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

Arbutus Contact Information

Investors and Media

William H. Collier
President and CEO
Phone: 267-469-0914
Email: ir@arbutusbio.com

Pam Murphy
Investor Relations Consultant
Phone: 267-469-0914
Email: ir@arbutusbio.com

Antios Contact Information

Investors:

Lee Roth
Burns McClellan
lroth@burnsmc.com
+1 (212) 300-8331

Media:

Ryo Imai / Robert Flamm, PhD
Burns McClellan
rimai@burnsmc.com / rflamm@burnsmc.com
+1 (212) 300-8315 / +1 (212) 300-8364